

### REMARKS

The Office Action mailed June 10, 2004 has been received and carefully considered. Applicant notes that the Examiner has withdrawn the finality of the last Office Action mailed February 24, 2004 in which the Examiner indicated that the claims under examination were directed to allowable subject matter.

Claims 27-42 are currently pending, all of which stand rejected as unpatentable over U.S. Patent No. 5,658,329 to Purkait (Purkait). Applicant respectfully traverses the rejection.

Purkait was provided to the Examiner in an Information Disclosure Statement filed April 7, 2004. Applicant did not learn of this particular reference until it was recently cited by a different examiner in a co-pending U.S. application. While this reference was submitted to ensure that Applicant has fully complied with his duty of disclosure under 37 C.F.R. § 1.56, it is apparent that this patent seems to be a U.S. equivalent of EP 0 727 232 to Brunstedt et al. (Brunstedt), which was previously submitted to the Office in an Information Disclosure Statement filed April 11, 2002. (Please note that the Brunstedt patent claims priority to U.S. Application No. 389,751, which subsequently issued as the Purkait patent.) In fact, it is also apparent that the text of Purkait is substantially the same as Brunstedt; those portions of Purkait cited by the Examiner against the claims in the current Office Action are found verbatim in Brunstedt.

Applicant notes that the Examiner already used Brunstedt to reject the claims and that these rejections have already been overcome. In an Office Action mailed May 6, 2003, the Examiner rejected the claims in view of Brunstedt, to which Applicant responded on November 6, 2003. A final Office Action was mailed February 24, 2004 in which the rejection in view of

Brunstedt was withdrawn, the claims were said to be directed to allowable subject matter, and the only rejections were provisional obvious-type double patenting rejections, which Applicant obviated by submitting terminal disclaimers in a response filed May 24, 2004.

As Applicant has not amended the claims since the Examiner withdrew his rejection in view of Brunstedt, Applicant respectfully submits that the claims remain directed to allowable subject matter in view of Purkait for the same reasons previously presented, which are incorporated herein by reference. Some of these reasons are elaborated on below.

Specifically, nowhere does Purkait teach, disclose or suggest that the filling material alone may be injected or otherwise placed in direct contact with the body. In fact, Purkait clearly teaches away from the claimed invention by teaching that the filling material must be placed in a compatible shell material to prevent substantial leakage or bleeding of the filling material. The shell is selected particularly for its compatibility in preventing the filling material from leaking into the body. Col. 3, lines 62-66. This suggests that Purkait's filling material, as its name implies, should not have direct contact with soft tissue, unlike Applicant's claimed prosthetic device which is injectable into soft tissue.

Any filling material which may leak from the shell of Purkait's invention is apparently either excreted or metabolized. Col. 4, lines 47-54. Again, this clearly teaches away from Applicant's claimed invention. While the claimed invention is injectable into soft tissue, any contact with the tissue by the filling material of Purkait is clearly accidental and is subsequently eliminated from the body by excretion or metabolization.

For similar reasons, a person ordinarily skilled in the art who develops a filling material to be contained within a shell would not have the same motivations as a person developing a

prosthetic device which is injectable into soft tissue. A material which is injectable into soft tissue presents a host of considerations, including various desirable physical properties and biocompatibility aspects, which would not be considered by one developing a filling material that is contained within a shell and not in direct contact with tissue.

Thus, Purkait does not teach, disclose, or suggest every element of Applicant's claimed invention, nor would one skilled in the art be motivated to modify Purkait to arrive at the claimed invention. A modification of Purkait's disclosure involving separation of the filling material from the shell, and the use of the filling material alone (contrary to Purkait's explicit teaching) could only have been made with the benefit of hindsight provided by Applicant's own invention. The use of hindsight in patentability analysis is erroneous as a matter of law. *See In re Dance*, 48 U.S.P.Q.2d 1635 (Fed. Cir. 1998).

Because a *prima facie* case of obviousness has not been established, Applicant respectfully submits that this rejection should be withdrawn.

**CONCLUSION**

For at least these reasons, Applicant requests that the Application be allowed and passed to issue. In the event any outstanding issues remain, Applicant would appreciate the courtesy of a telephone call to Applicant's undersigned representative to resolve such issues in an expeditious manner.

This Amendment and Response has been filed within three months of the mailing date of the Office Action, and it is believed that no fees are due. If any additional fees are determined to be due, the Commissioner is authorized to charge those fees to the undersigned's Deposit Account No. 50-0206.

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Respectfully submitted,

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